A Dissertation On

EFFICACY OF SANJIAO AND REN MERIDIAN MASSAGE ON BLOOD SUGAR LEVEL AMONG TYPE 2 DIABETICS - A RANDOMIZED CONTROL TRIAL

Submitted By

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The proposal is APPROVED.

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LIST OF ABBREVATIONS

PARTICULAR	ABBREVIATION
Type 2 diabetes mellitus	T2DM
Glycosylated hemoglobin	HbA1c
World health organization	WHO
Traditional Chinese Medicine	TCM
Fasting plasma glucose	FPG
Fasting Blood Glucose	FBG
2-hour Plasma Glucose	2 H PG
Post Prandial Blood Sugar	PPBS
Oral glucose tolerance test	OGTT
Transient ischaemic attack	TIA
Complementary and alternative medicine	CAM
American Diabetes Foundation	ADA
Statistical Package for Social Services	SPSS

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ABSTRACT

OBJECTIVE:

To understand the change in blood glucose level and HbA1c following meridian massage

BACKGROUND:

Diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels.

In acupuncture, there are many studies on its efficacy on diabetes. My study aims to understand the efficacy of meridian massage on diabetes

DESIGN AND METHOD:

60 subjects were randomized Using computerized number generation method into Group A (meridian massage; N = 30) and Group B (control; N= 30). The Subjects of Group A received meridian massage once in a week for 3 months along with their regular allopathic medications and Group B continued their allopathy medicines. Data was collected before and after treatment through blood glucose test and HbA1C.

RESULTS:

Meridian massage intervention showed statistically significant changes in fasting blood sugar level (p = 0.001), postprandial blood sugar level (p = 0.001) and HbA1C (p = 0.001).

CONCLUSION:

This trial suggested that meridian massage along with conventional medications is better in reducing serum glucose level and HbA1C level in type 2 diabetes.

INTRODUCTION

1. INTRODUCTION

Diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels (Diabetes care .2011)(WHO 2016).

Globally, an estimated 422 million adults are living with diabetes mellitus. According to the latest 2016 data from the World Health Organization (WHO). Diabetes prevalence is increasing rapidly; previous 2013 estimates from the International Diabetes Federation put the number at 381 million people having diabetes. Type2 Diabetes makes up about 85-90% of all case [*Williams textbook of endocrinology* (12th ed.)].

Until recently, India had more diabetics than any other country in the world, according to the International Diabetes Foundation. It affects more than 62 million Indians. Approximately 25.8 million people of all ages in the United States have diabetes (8.3 % of the population). Out of the 25.8 million people, 18.8 million people have been diagnosed, and 7.0 million have not been diagnosed (National Diabetes Info. Clearinghouse, 2013). Risk factors such as aging, sedentary lifestyle and obesity are the general cause of significant complications, most commonly targeting African-Americans, Latinos, Native Americans and Asian Americans (Copstead & Banasik, 2010). Family history of type 2 diabetes mellitus (T2DM) in a first-degree relative may lead to

patients acquiring the disease, but obesity causing increased levels of hyperlipidemia (high levels of fat in the blood) contributes to a majority of diabetic complications (Copstead & Banasik, 2010).

Diabetes Mellitus consists of a number of diseases involving abnormalities in insulin production and sensitivity. Insulin is a hormone produced in the body by the pancreas that aids in the uptake of glucose into cells. However, in patients with diabetes mellitus, the pancreas is either unable to produce enough insulin or insulin receptors on the cell's membrane are unable to bind insulin for uptake. This results in the cell's inability to carry out its metabolic functions due to the reduced influx of glucose entering the cell. Glucose provides the cells in the human body with the energy needed to accomplish physical as well as cognitive everyday tasks. With a decrease in the uptake of glucose by the cells, it accumulates in the bloodstream, which leads to hyperglycemia, a rise in the blood glucose levels. This clinically manifests as polydypsia (increased hunger), polyphagia (increased thirst), and polyuria (frequent urination) (Copstead & Banasik, 2010). Unfortunately, these symptoms do not become apparent at the time hyperglycemia develops, until there is a reduction in both insulin sensitivity and beta cell function. Overtime, continued hyperglycemia results in chronic complications such as diabetic neuropathy, a group of nerve disorders caused by diabetes (neuro-related to nerves, -pathy, disease), high blood pressure and cardiovascular diseases (National Diabetes Info. Clearinghouse, 2009).

Symptoms that arise from T2DM are an indicator for the disease, but may vary because some symptoms may appear more gradually than others. Due to this, the American Diabetes

Association has recommended screening guidelines to be followed. A diagnosis of T2DM is classified by a fasting plasma glucose level of 126 milligrams and confirmed with a secondary test (Copstead & Banasik, 2010). Glycoslated hemoglobin (HbA1c) is used to measure the plasma glucose concentration over a prolonged period of time (Copstead & Banasik, 2010). The A1c test is based on the attachment of glucose to hemoglobin, the protein in red blood cells that carries oxygen (Dubowsky, 2012). Since glycoslated hemoglobin indicates levels of glucose for up to three months, testing A1c levels is helpful in long-term management. The expected A1c levels in healthy individuals are 5.6% or below, whereas diabetic patients exhibit A1c levels 6.5 % or higher (Lukman et al. 2007 & Dubowsky, 2012). In addition, Alc levels of 5.7 % to 6.4% increase the risk of developing diabetes in the future (Lukman, He & Hui, 2007). A1c should be monitored every 3 months until it is less than 7.0 % and then rechecked every 6 months (Nestler, 2002). Proper testing and treatment, including education, are prescribed to patients to maintain lower glucose levels and prevent further deterioration of organs that can lead to chronic complications. Type 2 diabetes mellitus is a chief concern for patients, health care providers and health care systems around the globe. Individuals with type 2 diabetes mellitus exhibit clinical and subclinical symptom of anxiety more frequently than people without diabetes. Anxiety is traditionally associated with poor metabolic outcomes and increased medical complications among those with type 2 diabetes mellitus. Hence it is proposed link between anxiety and diabetes; offer an innovative and evidence based collaborative care for anxiety and diabetes in primary care.(BICKETT&TAPP,2016).

Mental state affects the food intake and the blood glucose levels .depression and/or anxiety are risk factors for the development of diabetes (Bystritsky et al.,2014)

Todays clinicians are presented with an extensive range of oral anti diabetic drugs for type 2 diabetes .neither sulphonylureas nor biguanides are able to appreciably alter the rate of progression of hyperglycemia in patients with type 2 diabetes. Preliminary data suggests that thiazolinediones may provide better long term glycaemic stability are currently being tested in clinical trials; current evidence, while encouraging, is not conclusive. However, intensive lifestyle intervention can be more effective than drug therapy; no anti – diabetic drugs are presently licensed for use in pre-diabetic individuals.(Krentz & Baily,2005).

Despite, implementation of interventions based on traditional risk factors ,the incidence of diabetes continues to rise. It has been estimated that modifiable risk factors including obesity, physical inactivity, diet quality, smoking, hypertension and abnormal cholesterol levels are the major risk factors for type 2 diabetes mellitus. (murea et al.,2012 spring).

Acupuncture and chinese herbal medicine have been used for over 2000 years to treat diabetes(Dharmananda,2002).TCM have long recognized the clinical manifestations of diabetes mellitus as a specific disorder under the name Xiao Ke,wasting and thirsting disease. References in the Nei Jing,the pre – eminent classic of chinese medicine ,to wasting and thirsting disease are scattered through 14 books of this classic, which elaborates causes and mechanisms,clinical manifestations and treatment (Flaws,Kuchinski & Casanas,2002).

In china ,acupuncture is used in conjunction with western drugs to treat diabetes. The combination helps reduce pharmaceutical medication dosage and rduce the side effects . Acupuncture aims to optimize the bodys ability to function normally.clinical and experimental

studies have demonstrated that acupuncture has a beneficial effect on lowering serum glucose levels(covington,2001).

According to the syndrome differentiation in TCM ,the cause for diabetes is an imbalance in the triple burners. Traditionally it is called as Xiao-ke, while stagnation of Qi or imbalance of yin and yang in any of the burners gives raise to the symptoms of diabetes like excessive thirst (polydypsia), excessive hunger (polyphagia) and excessive urination (polyuria)[4].

Sanjiao is the energy channel which is located 'separately from the zang-fu organs and inside the body'. It is divided into three parts: the upper, middle and lower jiao (burners). Clinically, the term upper, middle and lower jiao are often applied to generalise the functions of the internal organs of the chest, abdominal and pelvic cavity. Its main functions are to govern various forms of qi and serve as the passage for the flow of yuan qi and body fluid . Yuan qi originates in the kidney, but requires the sanjiao as its pathway for distribution in order to stimulate and promote the functional activities of the zang-fu organs and tissues of the whole body[5].

REN MERIDIAN: Running along the midline of the abdomen and chest, going upward to the chin, the REN meridian meets all the yin meridians. Its function is to receive and bear the qi of the yin meridians[5].

Previous study has shown that acupuncture effectively lower the serum glucose levels (Covington,2001) There are no studies conducted on meridian massage for diabetes. Current

study was conducted to evaluate the effect of meridian massage on blood glucose and HbA1c level in type 2 diabetic peoples.

AIMS & OBJECTIVES

2. AIM & OBJECTIVE

Aim: To understand the effect of sanjiao meridian massage on blood glucose levels of type2 diabetic subjects.

Objective:

To understand the change in blood glucose level and HbA1c following meridian massage.

REVIEW OF LITERATURE

3. REVIEW OF LITERATURE

This literature review chapter will commence by providing perspectives regarding the types of diabetes and tests of diabetes. Those sections will be followed by consideration of the history of diabetes and Chinese medicine perspectives regarding diabetes. The use of acupuncture points, meridian massage, ear acupuncture points as well as nutritional factors will also be engaged.

DIABETES MELLITUS

There are 3 main forms of diabetes (Stoppler, 2012). Type 1 results from the body's failure to produce insulin, usually referred to as insulin dependent diabetes or juvenile diabetes. Type 2 results from insulin resistance, in which cells fail to, use insulin properly. This is known as non-insulin dependent diabetes or adult onset diabetes. Gestational diabetes occurs when pregnant women without a previous diagnosis of diabetes develop a high blood sugar level. It may precede development of Type 2 diabetes.

Diabetes is on rise: no longer a disease of predominately rich nations, rather the prevalence is steadily increasing everywhere, most markedly in the world's low and middle-income countries (WORLD HEALTH ORGANIZATION, 2016) Type 2 diabetes is the most common type of diabetes, usually occurs in adults, but is increasingly seen in children and adolescents. Although the exact causes for the development of type2 diabetes are still not known, there are several important risk factors includes excess body weight,

physical inactivity and poor nutrition (INTERNATIONAL DIABETES FEDERATION,2105) severe and sustained emotional stress creates a physiological burden through increased sympathetic activity and higher energy demand. This may lead to increased oxidative stress and lead to development of metabolic syndrome. Emotional stress has been shown to contribute to the onset, progression and control of type 2 diabetes. Stress management and bio-feedback assisted relaxation have been shown to improve glycemic control.

Untreated diabetes can cause many complications (Tang 2009). Acute complications include diabetic ketoacidosis and nonketotic hyperosmolar coma. Serious long-term complications include cardiovascular disease, chronic renal failure and diabetic retinopathy. Adequate treatment of diabetes is very important, as well as lifestyle changes that include proper diet and exercise, stop smoking and maintain a healthy body weight.

INCIDENCE & PREVALENCE

The Prevalence of diabetes has been steadily increasing for the past three decades; mirroring an increase in prevalence of overweight and obesity. The number has nearly quadrupled since 1980.(WORLD HEALTH ORGANIZATION,2016) India leads the world with largest number of diabetes ,earning the dubious distinction of being termed "DIABETES CAPITAL OF THE WORLD" (mohan et.al., 2007) India is second to china which is home for more number of diabetes in the world(GUPTAL et al.,2015)

South Asian people originating from Pakistan, Bangladesh or India, experience 50% higher risk for developing type 2 diabetes compared with other populations, irrespective of whether they live in South-Asia or western countries.(BHURJI et al.,2016).

It raised from 108 million in 1980 to 422 million people with diabetes in the year2014. The global prevalence of diabetes, among the adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014. In the year 2015, an estimated 1.6 million deaths were caused by diabetes. WHO projects that,diabetes will be the 7^{th} leading cause of death by the year 2030.(WORLD HEALTH ORGANIZATION,2017).

In the South Asia region, it was estimated that about 78.3 million people aged between 20-79 years were affected with diabetes in the year 2015 and the number is projected to raise 14.2 million by the year 2040. (INTERNATIONAL DIABETES FEDERATION.,2015).

Preliminary results from a large community study conducted by the Indian council of medical research (ICMR) revealed that, lower proportion of the population is affected in the status of Northern India [Chandigarh -0.12 million , Jharkhand -0.96 million]as compared to Maharashtra[9.2 million] and Tamil nadu[4.8 million].The national urban survey conducted across metropolitan cities of India also reported similar trend which is: Eastern india [Kolkata-11.7%].Northern India[Kashmir Valley-6.1%, New Delhi-11.6%], West India [Mumbai-9.3%],South India[Cehnnai-13.5%, Hyderbad-16.6% ,Bangalore-12.4%].(Kaveeshwar & Cornwall,2014).

Genetic predisposition combined with lifestyle associated with urbanization and globalization contributes to the rapid rise of diabetes burden in India. Moreover type 2 diabetes mellitus appears to occur at least a decade earlier in Indian than in European Population. According to American Diabetes Association Criteria, the Prevalence according to WORLD HEALTH ORGANIZATION Criteria was 5.9% in urban and 2.7% in rural areas. The economic burden due to diabetes in India is among the highest in the world. However the real burden of diabetes is due to its micro-vascular complication, which leads to increased mortality and morbidity. (JOSHI.,2015)

Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes. Ninety percent of all patients diagnosed with diabetes are type 2. As of 2010 there are approximately 285 million people with the disease compared to around 30 million in 1985 (Smyth, Heron 2006). Long-term complications from high blood sugar can include heart disease, strokes, diabetic retinopathy where eyesight is affected, kidney failure that may require dialysis and poor circulation of limbs leading to amputations. The acute complication of ketoacidosis, a feature of type 1 diabetes, is uncommon (Fasanmade, Odeniyi & Ogbera, 2008).Type 2 diabetes can have a slow onset, and early symptoms can be confused with signs of stress, being overweight or a poor diet. It is known as a silent killer because of its easy - to - miss symptoms (Collazo-Clavell, 2013).

The best way to pick up on it is a blood, test but some of the common symptoms are:

- Increased urination and excessive thirst. These two symptoms go hand in hand and are the body's ways of trying to manage high blood sugar.
- Weight loss. Overly high blood sugar levels can cause rapid weight loss, about 10-20 pounds over a two to three month period. Since the insulin hormone is not able to get insulin to the cells, the body starts breaking down protein from the muscles as an alternate source of fuel. With the kidneys working overtime to eliminate the excess sugar, this then creates a further loss of calories.
- Hunger. This can come from sharp peaks and lows in blood sugar levels.
- Itchy Skin. Perhaps the result of poor circulation. Acanthosis nigricans is also another sign of diabetes.
- Slow healing.
- Yeast infections.
- Fatigue and irritability
- Blurry vision. This symptom is reversible once blood sugar levels are returned to normal or near normal.
- Tingling or numbness in hands and feet. If the symptoms are recent, they are likely to be reversible (Collazo-Clavell, 2013).

TESTS FOR DIABETES

TABLE: 1 DIAGNOSTIC CRITERIA*:(american diabetes association., 2017)*

Fasting plasma glucose(FPG)> 126 mg/dl(7.0 mmol/L).Fasting is defined as no caloric intake for at least 8 hr*
2-hour Plasma Glucose(2-h pg)> 200 mg/dl (11.1 mmol/L) during an Oral Glucose Tolerance Test(OGTT). The test should ne performed as described by the WHO. Using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.
HbA1C> 6.5% (4.8 mmol/mol) the test should be performed in a laboratory using a method that is NGSP1 certified and standardized to the DCCT2 assay.* In a patient with classic symptons of hyperglycemia or hyperglycaemic crisis, a random plasma glucose> 200 mg/dL(11.1 mmoL/L).
In the absence of unequivocal hyperglycemia , results should be confirmed by repeat testing.

1-National Glycohemoglobin Standardization program

2-Diabetes Control and Complications Trial

TABLE 2: ORAL GLUCOSE TOLERANCE TEST(OGTT): *(frier & fisher 2010)*

How to perform an oral Glucose Tolerance(OGTT)

Preparation before the test

- Unrestricted carbohydrate diet for 3-days
- Fasted overnight for at least 8 hrs
- Rest for 30 mins
- Remain seated for the duration of the test, with no smoking

Sampling

- Plasma glucose is measured before and 2 hrs after 75 g oral glucose drink

Interpretation (venous Plasma Glucose)

	Fasting	**2hrs-after glucose load**
Fasting Hyperglycemia	**6.1-6.9 mmoL/L (110-125 mg/dL)**	**<7.8 mmol/L (<140mg/dL)**
Impaired Glucose Tolerance	**<7.0 mmoL/L (<126 mg/dL)**	**7.8-11.0 mmoL/L 140-199 mg/dL**
Diabetes	**>7.0 mmoL/L (> 126 mg/dL)**	**>11.1 mmoL/L (>200mg/dL)**

Indications for the diabetes screening in asymptomatic individuals include the following criteria: (khardori ., 2107).

- Sustainer blood pressure of > 135/80 mm Hg
- Overnight and one or more other risk factor for diabetes (eg:blood pressure 140/90mmHg, HDL level < 35 mg/dL,triglyceride level> 250 mg /dL.

ADA recommends screening at age of 45 age in the absence of the above criteria**.** Several blood tests are used to check for diabetes, but a single test result is never enough on its own. According to the World Health Organization (World Health Organization report, 2007) patients should be told they have diabetes if:

- Blood sugar levels as measured by a fasting plasma glucose test are equal to or greater than 126 mg/dL.
- Diabetes symptoms exist and glucose levels measured at random are equal to or greater than 200 mg/dL.
- Glucose is equal to or greater than 200 mg/dL during an oral glucose tolerance test.

The American Diabetes Association (American Diabetes Association, 2010) also suggests that if test results indicate diabetes, testing should be repeated on a different day to confirm the diagnosis. If a random blood test has found glucose equal to 200 mg/dL or above, the confirming test used should be a fasting plasma glucose or an oral glucose tolerance test.

The development of type 2 diabetes is caused by a combination of lifestyle and genetic factors (Riserus, Willett & Hu 2009). While diet and obesity can be controlled, other factors such as increasing age, female gender and genetics are not (Williams textbook of Endocrinology, 12th ed). The effect of sleep on metabolism has also been linked to type 2 diabetes (Touma & Pannian 2011). A poor intrauterine environment can also result in an

increased predisposition to obesity and diabetes in offspring that can transfer from daughters to granddaughters across generations (Nathanielsz, 1999).

Treatment for Type 2 diabetes requires a life-long commitment to:

- Blood sugar monitoring
- Healthy diet
- Regular exercise

Risk factors:

Though researchers fully don't understand why some people develop type 2 diabetes and others do not, however it is clear that certain factors increase the risk of developing type 2 diabetes which weight , fat distribution , physical inactivity , family history race, age, pre-diabetes ,gestational diabetes and polycystic ovarian syndrome (mayo clinic.,2016)

I. **Weight**: Overnight being the primary risk factor to develop diabetes though people need not to be overweight to develop diabetes. If more fatty tissue present in a body more resistant the cells become to insulin.

II. **Fat distribution**: If there is more fat the deposition in or around the abdomen greater is the risk to develop type 2 diabetes compared with the fat deposition elsewhere(hips/thighs) in the body.

III. **Inactivity:** Physical activity helps to control weight by using glucose as energy and makes cell more sensitive to insulin, physical inactivity or less activity increase the risk of type 2 diabetes.

IV. **Family history:** Greater is the risk to develop diabetes if the parents/siblings has type2 diabetes.

V. **Race:** Although it is not clear why certain race have greater incidence ,certain race like blacks, Hispanics, American Indians Asian American are more likely to develop type 2 diabetes compared with that of whites.

VI. **Age**: Older the individual more risk is to develop type 2 diabetes due to less exercise ,lose muscle mass and weight gain , especially after the age of 45 . But more recently there is a dramatic increase in the incidence of type 2 diabetes even among children, adolescent and younger adults.

VII. **Pre-diabetes**: Is a condition in which blood sugar level is higher than normal, but no high enough to be classified as diabetes, often may progress to type 2 diabetes.

VIII. **Gestational Diabetes**: If a women gets diabetes during pregnancy of is the she gives birth to baby weighing more than 9 pounds (4 kilogram), risk for developing type 2diabetes increases

IX. **Polycystic ovarian syndrome**: Women having PCOS-a condition characterized by irregular menstrual cyle,excess bodily hair growth and obesity, increases the risk of diabetes

COMPLICATIONS

Micro vascular/neuropathic complications

Retinopathy-cataract,impaired vision

Nephropathy-protein loss, renal failure

Peripheral neuroathy- sensory losss,motor weakness

Automatic neuropathy- postural hypotension, vomitin, diarrhea

Foot disease – ulceration , arthropathy

Macro vascular complication

Coronary circulation – Myocardial ischaemia/ infaraction

Cerebral circulation – Transient ischaemic attack(TIA),Stroke

Peripheral circulation-claudication, gangrene,amputation

Other Possible complication includes the following:(mayo Clinic.,2016)

Hearing impairment- Hearing problem are more common in people with diabetes

Skin conditions- Diabetes makes more susceptible to skin problem, includes bacterial & fungal infections

Alzheimer's disease-Type 2 DM may increase the risk of Alzhemier's poorer the blood control greater is the risk , but the exact connection between the 2 still remains unclear

TRADITIONAL CHINESE MEDICINE

Key Concepts Within TCM

Qi

Qi (pronounced "chi") is translated into English as vital energy. It is defined in terms of function rather than as a discrete substance, and it is what animates us and allows us to move and maintain the activities of life. The origins of Qi include "con-genital"' (prenatal) Qi—that which is inherited from our parents—and "acquired" Qi—that which is incor-porated from food and air. , *(*Congdon & Weed, 1983)

Two major patterns of disharmony are associated with Qi. Deficient Qi occurs when there is insufficient Qi to perform the functions of life. Deficient Qi may affect one or more organs or the entire body. If the latter occurs, then the patient may experience lethargy, fatigue, and lack of desire to move. Stagnant Qi refers to impair-ment of the normal movement of Qi through the meridians (see discussion below) and may result in aches and pains in the body. *(*Congdon & Weed, 1983).

Meridians

Meridians are the channels or path-ways through which Qi is constantly flowing and circulating throughout the body. There are 12 regular meridians and 8 extra or "curious" meridians. The 12 main meridians correspond to 12 major functions or "organs" of the body (such as liver, kidney, heart).

The Chinese concept of organs corresponds loosely to the Western concept. TCM associates specific functions, symptoms, emotions, colors, and tastes with each organ, whereas the Western view is limited primarily to function.

Qi must flow in the correct quantity and quality through the meridians and organs for health to be maintained. Acupuncture, the insertion of thin, solid metal needles, is performed on 1 or more of the 361 acupuncture points distributed along the meridians in order to regulate and promote the proper flow of Qi (St. Louis, Mo., Mosby, 2000). Other techniques may be used to stimulate acupuncture points, such as moxibustion, in which the herb "moxa" (Artemesia vulgaris) is used to warm the acupuncture point either above or on the skin. Applied pressure (acupressure), lasers, and magnets also may be used to stimulate acupuncture points.

Jing

Jing, usually translated as "essence," is the substance that is the underpinning of all organic life. Qi is responsible for the ongoing day-to-day movements and function of the body, whereas Jing can be considered an individual's constitutional makeup. According to TCM, Jing is stored in the kidneys (Congdon & Weed, 1983).

Shen

Shen is considered to be the psyche or spirit of the individual. Shen is the vitality behind Jing and Qi in the human body. The three elements together: Qi, Jing, and Shen are referred to collectively in TCM as the "Three Treasures" and are believed to be the essential components of life (St. Louis, Mo., Mosby, 2000).

Blood

According to TCM, the major activity of the blood is to circulate through the body, nourishing and moistening the various organs and tissues. Disharmonies of the blood may manifest as "deficient" blood or "congealed" blood. If deficient blood exists and affects the entire body, the patient may present with dry skin, dizziness, and a dull complexion. Congealed blood may manifest as sharp, stabbing pains accompanied by tumors, cysts or swelling of the organs (i.e., the liver) (Congdon & Weed, 1983). The key organs associated with blood are the heart, liver, and spleen.

Fluids

Fluids are bodily liquids other than blood and include saliva, sweat, urine, tears, and semen. Fluids act to moisten both the exterior (skin and hair) and the internal organs. Disharmonies of fluids may result in dryness and excess heat. The key organs involved in the formation, distribution, and excretion of fluids are the lungs, spleen, and kidneys (Lippincott Williams and Wilkins, 1999).

History

Diabetes is one of the first diseases described (Ripoli & Leutholtz, 2011) 3000 years ago by the ancient Egyptians (Ahmed 2002), mentioning "too great emptying of the urine" (Poretsky, 2009). Indian physicians around the same time identified the disease and classified it as madhumeha or 'honey urine' (Poretsky, 2009). The term "diabetes" or "to pass through" was first created by Araetus of Cappadocia, 81-133 AD (Ahmed 2002). Later the word "mellitus" was added by Thomas Willis in England in 1675 after rediscovering the sweetness of urine of patients, first noticed by doctors in India (Ahmed 2002).

In 1776, Matthew Dobson confirmed that the sweet taste of urine of diabetics was due to excess of a kind of sugar in the urine and blood. It was in 1857 in France, that Claude Bernard established the role of the liver in glycogenesis and the concept that diabetes is due to excess glucose production. The role of the pancreas in pathogenesis of diabetes was discovered by Mering and Minkowski in Austria in 1889.

This discovery then constituted the basis of insulin isolation and clinical use by Banting and Best in Canada in 1921 (Ahmed 2002).

Chinese Medicine and Diabetes

Chinese Medicine has been treating diabetes for thousands of years. Called Xiao-Ke, or "wasting and thirsting disease" (Flaws, Kuchinski & Casanas, 2002), it was first described in one of the oldest books about Chinese medical theory. The Nei Jing states that diabetes occurs typically among wealthy people: "You ask them to refrain from a rich diet, advice which they may resist." This description fits Type 2 diabetes (Joswick, 2013).

The studying and understanding of wasting and thirsting spanned a period of 2000 years of recorded medical history in China (Zhang et al., 2010). The process of understanding, identification and naming of wasting and thirsting, as represented by The Yellow Emperor's Classic of Internal Medicine (Huang Di Nei Jing), 475 B.C. – 8 A.D. (Warring States Period – Western Han Dynasty); the documentation of wasting and thirsting as represented by Treatise on Febrile and Miscellaneous Disease (Shang Han Za Bing Lun), 9 A.D.-280 A.D. (Eastern Han Dynasty-Three Kingdoms); the understanding of "sweet urine" and its documentation in Ancient and Modern Proved Formulae (Gu Jin Lu Yan Fang), 265 A.D.-1368 A.D. (West Jin Dynasty-Yuan Dynasty); and the connection between wasting and thirsting and diabetes as represented in The Integration of Traditional Chinese Medicine and Western Medicine (Yi Xue Zhong Zhong Can Xi Lu), 1368 A.D.-1949 A.D. (Ming Dynasty – Republic of China) (Zhang et al., 2010).

The Yellow Emperor's Classic of Internal Medicine records symptoms of "three increases and one decrease," i.e. polydipsia, polyuria and polyphagia and weight loss (Zhang et al., 2010, pg 42). Around 2000 years ago, upon identifying the onset of primary symptoms, diabetes was then diagnosed as xiao-ke (Zhang et al., 2010). After wasting and thirsting was classified as a disease, the development, diagnosis and treatment were elaborated in this book. Twenty-five entries on wasting and thirsting were recorded in this book, which included the name Xiao-ke, symptoms (three increases, one decrease and complications), pathogens (obesity, greasy foods), pathologies (yin-yang theory, five elements), therapies (acupuncture, herbs), healthcare (diet control), diagnosis (pulse-taking) (Gao, 2002).

In the Sui and Tang dynasties (581-907 A.D.), the diagnosis and treatment focused on markers (sweet urine), treatment, prevention, maintenance and diet (Zhang et al., 2010). "Sweet urine" was considered an important diagnostic symptom of wasting and thirsting in Ancient and Modern Proved Formulae written by Li Yan Zeng (545 A.D.649 A.D.) This method of symptom diagnostics was noted by other doctors like Tao Wang in 752 A.D. in The Secret Medical Essentials of a Provincial Governor. In a case report, he identified sweet urine as an essential method of diagnosing diabetes (Dengben, 2004).

According to TCM, dryness and heat leading to qi and yin vacuity, is the main disease mechanism of diabetes mellitus (Flaws et al., 2002). This dryness and heat may be due to "natural endowment exuberance" (Flaws et al., 2002, p. 24) or insuffiency, dietary

irregularity, pyscho-emotional stress, unregulated "stirring and stillness" (Flaws et al., 2002, p. 24) and unregulated sexual activity. Prof. Zhang Su Qing stresses an original yin depletion and vacuity as the main type of natural endowment insufficiency (Zhao et al., 2001). Some people are born with less yin than others. Bob Flaws in his book "The Treatment of Diabetes Mellitus with Chinese Medicine" says, "The act of living is the transformation of yin into yang and the consumption of yin by yang in the same way a candle's flame transforms wax into light and also consumes that wax." (Flaws, et al., p. 23). The Nei Jing (Inner Classic) says, "[By] 40 years, yin is automatically half." (Flaws, et al., p.23). This statement helps explain why diabetes is primarily a condition associated with aging (Flaws et al., 2002). However, diabetes may also be associated with an inherent tendency to yang exuberance, commonly stomach yang exuberance. People with stomach yang exuberance develop large appetites and tend to overeat. If overeating leads to gaining weight and developing adipose tissue, that adipose tissue aggravates internal heat (Flaws et al., 2002). In addition, people with yang exuberance also tend to overwork and over a period of their lives, fail to conserve their qi and yin, thus damaging and consuming both through over-taxation. Irregular food intake in the form of over consumption of greasy, spicy and sweet foods and over consumption of alcohol, impairs the transportation and transformation functions of the Spleen and Stomach, which in turn generates internal heat. That generated heat consumes fluids thereby creating thirst and hunger. In the Simple Questions, (Su Wen), it is explained that "fat causes interior heat while sweetness causes fullness in the middle burner". The qi therefore rises and overflows and the condition changes into that of wasting and thirsting (Choate, 1999).

Prolonged emotional stress and disturbance may contribute to wasting and thirsting by hindering the flow of qi. Over thinking and anxiety damages the Spleen, causing the qi to bind in the middle, while anger, resentment and frustration leads to constrained Liver qi. This constrained Liver qi transforms into fire, which in turn consumes the yin of the Lung and Stomach (Choate, 1999). A passage from the Spiritual Axis (Ling Shu) Chapter 2 says, "The five inner (yin) organs are soft and weak and prone to symptoms of wasting heat. When there is something soft and weak, there must be something hard and strong. Frequent anger is hard and strong and the soft and weak are thereby easily injured." (Choate 1999, p. 5).

In Chinese Medicine, "stirring" refers to any movement in the body, whether it is mental-emotional, verbal or physical (Flaws, et al., 2002). Since movement in the body is empowered by Qi, it is easy to over consume and damage the Qi with excessive stirring, thus, in turn, damaging the Spleen. "Stillness" is the absence of stirring (Flaws, et al., 2002 pg 23). As a cause of disease, it can refer to mental-emotional, verbal or physical inactivity. Since excessive sitting damages the Spleen, inactivity can cause or aggravate Spleen vacuity. Physical activity promotes the movement of qi, blood and fluids in the body. Hence, physical inactivity creates depression of qi and blood leading to damp and phlegm accumulation and poor circulation due to blood stasis. "It is easy to see that, when it comes to stirring and stillness, too much or too little of either may contribute to the causation of diabetes mellitus" (Flaws et al., 2002, p. 23).

Excessive and unregulated sexual activity can lead to kidney qi and jing consumption and hence to heat in the lower jiao. This in turn leads to kidney yin deficiency. Wang Tao in his Wai Tai Mi Yao (Secret Essentials of the External Platform), "Wasting and Thirsting and Middle Wasting," says "Excessive bedroom affairs must result in kidney qi vacuity and consumption and the engenderment of heat in the lower burner. [This] heat leads to kidney dryness and kidney dryness leads to thirst." (Flaws, et al., p.23).

In sexual activity that leads to orgasm, qi and yang are both discharged and yin/ essence is consumed, leading to kidney qi and essence deficiency (Flaws, et al., 2002).

Sun Si Miao and Wang Tao, in their treatises written during the Tang dynasty, laid emphasis on the over use of longevity elixirs and tonics and their effect on the depletion of yin in the body, thus leading to wasting and thirst. In modern Western medicine, certain medications may cause or increase the incidence of diabetes. Certain diuretics and beta-blockers prescribed for lowering blood pressure can cause or aggravate diabetes, as can lithium, generally prescribed for bi-polar disorders, cause or aggravate nephropathy often associated with long term diabetes (Flaws et al., 2002). Long term use of antibiotics and corticosteroids, such as predinisone, can damage the Spleen, according to the understanding and logic of Chinese medicine. This in turn leads to Spleen deficiency and the various complications associated with Spleen deficiency, such as turbid dampness or damp heat (Flaws et al., 2002).

In this way, according to Chinese medicine, type 2 diabetes is the result of a number of factors, all of which lead to qi and yin deficiency with dryness and heat. When there is

considerable dry heat, it consumes Lung fluid, thereby creating a dry mouth and thirst. The tongue is red and the pulse is rapid. Heat in the Stomach and Spleen creates excessive hunger and appetite. Stomach Fire manifests as excessive hunger, bad breath and constipation. The tongue is red with a yellow coat and the pulse is rapid.

Overworking, prolonged stress or illness, excessive sexual activity and multiple pregnancies deplete essence, which in turn leads to Kidney Yin deficiency. Yin deficiency manifests as weight loss, frequent and copious urination, dizziness, blurred vision, sore back, itching and ulceration of the skin and vaginal itching. The tongue is red with little or no coat and the pulse is thin and rapid. Since, according to the principle that Kidney yin deficiency leads to Kidney yang deficiency, we then observe, in prolonged cases, Xiao Ke syndrome occurring when there is Kidney yang deficiency. The focus of the treatment can be established by analyzing which of the three organs is the most yin deficient, Lung, Spleen or Kidney and by concentrating on relieving deficiency heat from either the upper, middle or lower burner. The treatment for diabetes focuses on regulating the circulation of blood and Qi and balancing the organ systems to improve pancreatic function and address internal heat and the depletion of fluids (Sonmore, 2006.)

Common symptoms created by the depletion of body fluids and Qi are:

- Fatigue
- Lethargy
- Weight Loss
- Excessive thirst

- Excessive urination
- Excessive hunger
- Poor wound healing
- Infections
- Irritability
- Blurry vision

Scientific studies and clinical tests in international research centers in the past 10 years have shown that acupuncture can help diabetic patients in the following ways:

- Attenuate symptoms of polyphagia, polydypsia and polyuria
- Prevent slowing of motor nerve conduction
- Improve microcirculation and myocardial contractility
- Enhance blood outflow and regulate vascular peripheral resistance
- Induce secretion of endogenous beta-endorphin

Syndrome Differentiation

"TCM syndrome differentiation and evaluation standard of DM", "Guidelines of Prevention and Treatment of Diabetes by TCM, 2007," and "DM treatment using integrated traditional Chinese and Western medicinal therapy" have all been proposed for the TCM-mediated differentiation of the clinical stages of DM. In one study, stagnancy, heat, deficiency, and damage were thought to be the four stages of diabetes, and collateral damage existed through the course of the disease even before the diagnosis. T he collateral

damage in different degrees could be defined as “collateral qi obstruction, collateral qi stagnation, collateral blockage, and collateral damage.” The study also suggested that the TCM-mediated differentiation with the clinical stages of DM is indispensable. Therefore, we performed syndrome differentiation based on the clinical stages of diabetes.

SYNDROME DIFFERENTIATION OF DM

QI STAGNATION DUE TO LIVER DEPRESSION.

According to modern medical research, patients with diabetes often exhibit aggravated emotional tension, which is consistent Evidence-Based Complementary and Alternative Medicine with the theory of TCM that negative emotions could lead to diseases. Liver depression could lead to qi stagnation and result in some emotional symptoms. T his was the first stage of diabetes, and the characteristic was stagnancy. Therefore, soothing the liver and adjusting qi are the main therapeutic principles. This type of diabetic patients shows some emotional symptoms such as depressed mood, like frequent sighing, nervousness, distention, and fullness in the chest and rib-side. The patients usually have a pale tongue with thin white moss and a stringy pulse. Modified Xiao Chaihu decoction, a classic Chinese ancient prescription, was commonly used to treat this type of diabetic patients; some herbs like Bupleurum, Scutellaria baicalensis, Pinellia ternata, and Ginseng were included in this decoction.

LIVER AND STOMACH HEAT STAGNATION.

A symptom analysis of 2518 obese patients with type 2 diabetes demonstrated that there were 1332 cases of liver and stomach heat stagnation syndrome, accounting for 52.9% of all the cases, suggesting that it was an important type in diabetes syndrome differentiation. Liver and stomach heat stagnation belong to the stagnancy and heat stages of diabetes. The patients of this type showed some emotional and digestive symptoms such as irritability, distention and fullness in the chest and rib-side, drinking too much fluids and the production of increased urine, eating too much food, hunger, experiencing a bitter taste, dry mouth, and constipation. And patients usually have a red tongue, and a rapid and stringy pulse. Clearing stagnation-heat of liver and stomach is an important therapeutic principle for this type. A modified Da Chaihu decoction, one of classic Chinese ancient prescriptions recorded in Treatise on Cold Pathogenic and Miscellaneous Diseases, was used to treat such diabetic patients. Some Chinese herbs like Bupleurum, Chinese rhubarb, Scutellaria baicalensis, Citrus aurantium, Radix Paeoniae Rubra, and so forth were included in this formula.

PHLEGM AND HEAT STASIS.

A study by Gan et al. showed that phlegm and heat stasis syndrome was a common type in the early and middle stages of diabetes and accounted for more ratios particularly

in patients who smoked and drank alcohol. Zhou et al. investigated 344 patients with type 2 diabetes and found that 101 cases (29.4%) belonged to phlegm and heat stasis syndrome. This syndrome often appears in the "heat" stage of diabetes, and the patients are relatively obese because in the theory of Chinese medicine, "obese people tend to have copious phlegm." Patients with this type may have some symptoms such as abdominal obesity, a sense of chest suppression, abdominal distention, and dry mouth. They might also prefer cold drinks, drink much more fluids, and be irritable and have a bitter taste in their mouth as well as constipation. Patients also have a red and fat tongue with yellowish greasy moss, yellow urine, and a stringy and smooth pulse. Reducing heat and removing phlegm is the therapeutic principle in this syndrome, and a modified Xiao Xianxiong decoction, a classic Chinese ancient prescription, is used to treat such diabetic patients. Some Chinese herbs like rhizoma coptidis, Pinellia ternata, snakegourd seed, and so forth are included in this formula.

EXCESS HEAT IN THE STOMACH AND INTESTINE.

Both Tong and Wang's studies demonstrated that "*excess heat in the Stomach and intestine*" was one of main syndromes of diabetes. This syndrome generally occurs in the diabetic middle stage or in the "heat" stage. In the middle stage of diabetes, patients eat large amounts of food, which stagnate and form heat in the stomach and intestine. As such, its principal symptoms are abdominal fullness and distention, constipation, a bitter taste and dry mouth, halitosis, thirst with a desire for cool water, drinking and eating too much, and hunger. Patients usually have a red tongue with yellow moss and a rapid strong pulse.

To remove the heat, a modified Dahuang Huanglian Xiexin Decoction is regarded as the main prescription which includes Chinese rhubarb and rhizoma coptidis and so forth.

INTESTINAL DAMP AND HEAT SYNDROMES.

According to the findings of Zhao et al. in a study using classical prescriptions to treat different diseases, the Gegen Qinlian decoction could be used to treat type 2 diabetes with concurrent intestinal damp and heat syndromes, with a good clinical efficacy. An additional study showed that Gegen Qinlian decoction could significantly improve the intestinal damp and heat syndrome scores of patients with type 2 diabetes and could effectively control blood glucose with a success rate of 88.6%. Another study revealed that the morbidity of type 2 diabetes with damp and heat syndrome was 30.7% and that the location of disease was in Fu-organs. In addition, this syndrome has unique features. The intestinal damp and heat syndromes always appear in the diabetic middle stage or during the heat stage. Its principal symptoms are thirst with no desire to drink, hunger with no desire to eat, a bitter taste, a sticky and greasy sensation in the mouth, and abdominal distention. Patients also show a red tongue with yellow and greasy moss and a slippery pulse. When damp and heat affect the large intestine, smelly greasy stools might also form. To reinforce the spleen and stomach and remove the heat and dampness, a modified Gegen Qinlian decoction, one of classic Chinese ancient prescriptions, is used to treat such diabetic patients. Some Chinese herbs like kudzuvine root, Scutellaria baicalensis, rhizoma coptidis, and so forth are included in this formula.

DEFICIENCY OF BODY LIQUID DUE TO EXCESSIVE HEAT SYNDROME.

A study by Gan and Chen suggested that excessive heat injuring liquid syndrome was a principle syndrome of diabetes. Consistent with this, Zhang et al. reached the same conclusion after investigating 1490 cases of type 2 diabetes using clinical syndrome differentiation. The deficiency of body liquids due to excessive heat syndrome is more commonly found in the diabetic middle-late stage or the heat and deficiency stages. Impacted by the fire and heat pathogens from the early and middle stages of diabetes, qi is consumed and liquids are injured gradually. As such, its principle symptoms are dry throat and mouth, thirst with a desire for cool water, overeating and hunger, frequent maturation volume, irritability, bitter taste, red urine, and constipation. Patients also commonly have a red tongue with yellow fur and a rapid pulse. To sooth the heat and promote fluid production, a modified Xiaoke Wan or Baihu Tang, belonging to classic Chinese ancient prescriptions recorded in Treatise on Cold Pathogenic and Miscellaneous Diseases, is used to treat such diabetic patients. Some Chinese herbs like Gypsum, Rhizoma Anemarrhenae, Liquiritia Glycyrrhiza, and so forth are included in this formula.

DUAL DEFICIENCY OF QI AND YIN.

Based on her 40 years of clinical experience, Lin and Ni proposed a theory called III-type differentiation, which proposes that the dual deficiency of qi and yin syndrome was one of basic syndromes of diabetes. Many other professors, including Xu et al., Mao et al., and Li et al. also concluded that the dual deficiency of qi and yin syndrome was a

common syndrome of diabetes. The dual deficiency of qi and yin syndrome occurs in the late diabetic or the deficiency stage. The fire and heat pathogens further dissipate the primordial qi of zang-fu organs, and then the generalized qi is consumed. In addition, fire and heat pathogens scorch liquids and damage yin. Therefore, the main symptoms are dry throat and mouth, thirst with a large intake of fluid, fatigued spirit and lack of strength, shortness of breath and reluctance to speak, emaciation of the body, limp aching lumbus and knees, spontaneous and night sweats, feeling palm and arch fever, upset, palpitations, insomnia, a red tongue with scant liquids and thin white dry tongue fur, and a fine rapid pulse. Boosting qi and nourish yin is one of the important therapeutic principle in this type, and a modified Shengmai Yin decoction, a classic Chinese ancient prescription, is used to treat such diabetic patients. Some Chinese herbs like, Ophiopogon japonicas, Schisandra chinensis, ginseng, and so forth are included in this formula.

THE STAGE OF DIABETES COMPLICATIONS.

During the diabetic complications stages, treatment requires the combination of disease and syndrome differentiation due to its complexity. In general, the deficiency is increasingly aggravating, and so qi-blood-liquid deficiency and the function of internal organs decline. It belongs to late stage of diabetes; liver and kidney insufficiency and deficiency in both yin and yang are its endpoints. The main syndromes in this stage include insufficiency of the liver and kidney and detrimental yin and yang.

INSUFFICIENCY OF THE LIVER AND KIDNEY SYNDROME.

The main symptoms are urinary frequency, turbid unctuous and limp aching and lumbus and knees, which are accompanied by additional symptoms including blurred vision, dizziness, tinnitus, red tongue with some fur, and a fine rapid pulse. Modified Qiju Dihuang Wan, which includes the fruit of Chinese wolfberry, chrysanthemum, Chinese yam, and Cornus officinalis, is used to treat these diabetic patients by enriching the liver and kidney with essence and increasing blood supply.

Dual Deficiency of Yin and Yang Syndrome.

Patients with this syndrome exhibit symptoms including urinary and nocturia frequency, which can be accompanied by feeling palms and arches fever, being upset, dry throat or mouth, limp aching lumbus and knees, fear of the cold, icy cold limbs, and a forceless fine sunken pulse. Enriching yin and supplying yang is an important therapeutic principle; modified Jingui Shenqi decoction, which includes the Chinese herbs adhesive rehmannia dried root, Chinese yam, Fructus Corni, cassia twig, and monkshood, is commonly used to treat these diabetic patients.

Studies have shown that the characteristic patho-physiological mechanism of chronic diabetic complications is root deficiency and tip excess. Deficiency and static blood occur throughout several complications. The dual deficiency of qi and yin, phlegm turbidity, and static blood obstructing the network vessels form the common pathological basis of

diabetic chronic complications. Studies using the collateral disease theory have determined that static blood obstructing the collaterals is the pathological basis for diabetic micro-angiopathy; therefore, treatment should be aimed to promote blood circulation and remove obstruction in vessels throughout the whole process. A large number of clinical observations and scientific studies have confirmed that capillaries can be protected and diabetic micro-vascular complications prevented and treated using drugs that accelerate blood flow during early-mid diabetes.

Generally, treatments for diabetic complications should target phlegm, static blood, and additional pathological factors, except for insufficiency of the liver and kidney and dual deficiency of qi and yin, for more comprehensive and thorough evidence-based medicine

Acupuncture Points for Diabetes

Contemporary publications have extensive and detailed formulas dealing with type 2 diabetes. Jin Zhen Wang Le Ting (Golden Needle Wang Le Ting) compiled by Dr Yu Hui-chan and Dr Han Fu-ru, Dr Wang's students, was published in Beijing in 1984. Wang (1894-1990) was 89 years old when the Chinese edition from which this book has been created was first compiled in 1983. Nei Ke Zhen Jiu Pei Xue Xin Bian (A New Compilation of Acupuncture and Moxibustion for Internal Medicine) by Zhan Xi Wang, published in 1993 and Zhong Guo Zhen Jiu Chu Fang Xue (A Study of Chinese Acupuncture and Moxibustion Prescriptions) by Xiao Shao Qing, published in 1986, are some of the outstanding works that give us clear and concise prescriptions for treating

upper, middle and lower jiao wasting.

Upper Burner/Jiao

For injury of body fluids by Lung heat, the treatment principle is to strengthen the function of the Lung, tonify yin and clear heat. Clinical manifestations are excessive thirst, dry throat and mouth, dry cough, hoarse voice, night sweats, emaciation and flushed cheeks.

Points:

- Fei Shu BL 13: Clears excess or deficient heat from the Lung and upper jiao and tonifies Lung yin.
- Chi Ze LU 5: Clears heat from the Lung, alleviates cough and regulates water passages.
- Yu Ji LU 10: Clears Lung heat and benefits the throat.
- Gao Huang Shu BL 43: Nourishes blood and yin, tonifies deficiency, cools heatand treats night sweats. BL 43 tonifies Lung, Spleen and Kidneys and can be used in any of the three patterns of disharmony, but due to its location in theupper jiao, it is recommended for this pattern, especially when the deficiency is accompanied by deficiency heat.
- Zu San Li ST 36: Assists BL 13 in strengthening the Lung.

- Lian Quan REN 23: Stimulates the production of body fluids.
- Tai Xi KID 3: Tonifies the Kidneys, nourishes yin and supports the Lung.

If there is Lung and Kidney qi deficiency, add Guan Yuan REN 4, with supplementing method. If Lung and Stomach heat is intense, add San Yin Jiao, SP 6 and Nei Ting ST 44, using draining method.

Middle Burner/Jiao

For injury of yin by Stomach dryness the treatment principle is to clear Stomach dryness and heat and tonify yin. Clinical manifestations are: excessive appetite or propensity to hunger, halitosis, dry lips, painful swelling or bleeding of gums, constipation, burning sensation in the epigastrium.

Points:

- Zu San Li ST 36: Clears Stomach dryness and benefits Stomach yin.
- Nei Ting ST 44: Clears Stomach heat.
- Nei Guan PC 6: Regulates the middle jiao and clears heat.
- San Yin Jiao SP 6: Benefits the Stomach and tonifies yin and body fluids.
- Zhong Wan REN 12: Harmonizes the middle jiao and tonifies stomach.
- Pi Shu BL 20 and Wei Shu BL 21: Both benefit Spleen and Stomach.

- Wei Guan Xia Shu (M-BW-12) or Yi Shu (Pancreas Shu): Clears heat and generates fluids. First mentioned by Sun Si Miao in the Thousand Ducat Formulas in the 7th century for wasting and thirsting disorder.
- Tai Xi KID 3: Tonifies Kidneys and nourishes yin. Supports the yin of the whole body.

Lower Burner/Jiao

For exhaustion of Kidney essence and Kidney yin, the treatment principle is to strengthen the function of the Kidneys and nourish essence. The clinical manifestations are: excessive urination, lumbar pain, weakness of the legs, constipation, blurred vision, dizziness, poor memory, afternoon fever and nocturnal emission.

Points:

- Guan Yuan REN 4: Benefits essence, tonifies and nourishes Kidneys and benefits the Bladder.
- Qi Hai REN 6: Tonifies Kidney qi.
- Tai Xi KID 3: Tonifies Kidney and nourishes yin
- Ran Gu KID 2: Clears deficiency heat and regulates the Kidneys.
- SanYin Jiao SP 6: Benefits the Kidneys and nourishes yin.

- Shen Shu BL 23: Tonifies the Kidneys, nourishes yin and essence and treats excessive urination.
- Jing Men GB 25: (front-mu point of the Kidney) combines with its back-shu point Shen Shu BL 23 to tonify the Kidneys, benefit the water passages and control urination.(Choate, C. 1999; Flaws, et al., 2002).

Further points to supplement Kidney yin are Zhi Shi BL 52, Xin Shen BL 15, Shen Men HT 7, with even-supplementing even-draining method. When there is a pattern of both yin and yang deficiency, add Zhi Shi BL 52, Ming Men GV 4, with supplementing method and moxa on Ming Men (Choate, C. 1999; Flaws, et al., 2002). According to Li Yong Zhi and Meng Fan Yi, in their book Xiao Ke (Wasting and Thirsting 1995), the course of acupuncture treatments must be more than three months. The effects of these treatments, according to them, can be very high (Flaws et al.,2002).

If possible, treat as frequently as daily or every other day, with needles retained for 30 minutes (Choate, 1999).

Ear Acupuncture

Ear acupuncture for type 2 diabetes can be done at:

- Pancreas
- Liver
- Endocrine

- Triple Burner
- Kidney
- Heart.

The following points can be added according to predominant symptoms:

- For polydypsia: add Lung and Thirst Point.
- For polyphagia: add Spleen and Stomach.
- For polyuria: add Urinary Bladder.

If needling, it is important not to use more than 5-7 needles at a time, retaining needles for 20-30 minutes at a time. Treatments can be done every other day or at least three times a week. Press needles or ear seeds can also be used, taped over the points and stimulated by finger pressure several times a day (Flaws, 2002; Choate, 1999).

TCM Nutrition and Food Remedies for Diabetes

Chinese nutrition is an extremely important and integral part of Chinese medicine. It differs from modern Western nutrition in that it determines not only the prevention of disease and the maintenance of good health, but also plays a pivotal role in bringing about the remedy and cure for disease. It does that by determining the therapeutic property of foods rather than the effect of the chemical constituents of individual foods on the body. It

is well understood in Chinese nutritional therapy that all foods have a certain temperature, certain organ energies that they tonify and nourish and takes into consideration factors such as the individual's body type, age and vitality, time of year and geographic location and the method of preparation in determining the appropriate diet. Thus, in case of illness, rather than focusing only on the disease, the whole person can be addressed. Understanding and treating each person's personal imbalance and illness and the ability to adapt to the changing needs of an individual, is the basis of Chinese nutritional therapy (Flaws et al., 2002).

The root pattern of diabetes, as understood in Chinese medicine, is qi and yin deficiency with dryness and heat (Flaws et al., 2002). Therefore, when treating diabetes, it is important to tonify qi, nourish yin, and moisten dryness and clear heat. It is the sweet flavor within food that is responsible for tonifying and nourishing qi. Grains, legumes, fruits and vegetables all contain, to some extent, some sweet flavour that fortifies the Spleen and hence qi. Unfortunately, the sweeter the food, the more it generates fluids (Flaws et al., 2002). If more fluids are generated than the Spleen can transport and transform, these collect and create damp in the body thus damaging the Spleen and creating a Spleen deficiency. Therefore, it is important to remember that one cannot simply eat sweet foods to tonify qi. In fact, it is the overeating of sweet foods and sugars that has created the disease in a diabetic patient in the first place (Flaws et al., 2002).

Refined white sugars and other simple sugars ultimately convert to fat in the body (Pitchford, 1993). In type 2 diabetes, even though enough insulin is produced, the utilization in the cells of the body is blocked by the effects of a diet rich in fats (Olefsky et

al., 1974). This, in turn, causes Liver stagnation, which then creates a Spleen imbalance, thereby making pancreatic secretions such as insulin less effective (Pitchford,1993).

Foods high in "flavour" nourish yin, blood and essence (Flaws et al., 2002, pg 22), especially animal products such as meat, eggs and milk products. Flavour, according to Flaws, refers to "the clear part of the turbid from which yin is engendered and transformed" (Flaws et al., 2002 p 24). They are, however, difficult to digest and could, if not consumed in moderation, damage the Spleen and thus lead to internal damp. Animal products are essentially high in fats, and though people with yin deficiency need to eat more highly flavoured and fatty foods, such as duck, shellfish, beef, butter and milk, in diabetic patients, these foods, being warm and/or hot, will not only create damp but also heat (Flaws et al., 2002).

Diabetes occurring in a person who has overindulged in a diet of meat, fat and refined foods will exhibit not only a few yin deficiency symptoms but also signs of heat and excess, usually manifesting as being overweight and constipated, with red complexion and a thick yellow tongue coating (Pitchford, 1993). In Chinese medicine, every food has a temperature, "the effect the food has on yang heat within the body" (Flaws et al., 2002 p 24). Hence, foods those are cool or cold, and cleansing, should be added to the daily diet of excess type, hyperactive yang patients.

According to Bob Flaws, it is important for patients with diabetes not only to be careful about the harmonization of the five flavours but also to not eat foods that aggravate their condition in terms of their “pattern discrimination”. Patients should not overeat any of the specific flavours of sweet, spicy or salty, since sweet, as has been mentioned before, damages the Spleen. In the same vein, excess salt damages the kidneys and excess consumption of acrid, spicy foods creates internal heat and damages and consumes yin (Flaws et al., 2002).

The key is to be careful and mindful about consuming less food, especially foods that stress the Liver, weaken the Spleen, damage the Kidneys and consume yin and to eat only moderately sweet foods, limit the intake of greasy and fatty foods (meats, eggs, cheese, butter, excess oil, nuts and seeds), avoid “denatured” foods (refined white flour, hydrogenated, synthetic fats such as margarine and shortening and chemical ingredients). Diabetic patients should also avoid late night eating and complex food combinations. Small, frequent meals help to stimulate insulin production (Pitchford,1993).

MATERIALS AND METHODS

4. MATERIALS AND METHODS

STUDY SAMPLES:

A total number of sixty (60) subjects of both genders within age group of 35-55 years have participated in the study the subjects were screened through a routine medical checkup and those who satisfy diagnostic criteria of Type 2 diabetes mellitus were recruited for the study after getting informed consent.

DESCRIPTION OF POPULATION SUBJECTED FOR STUDY:

The study population was selected from the Out Patient Department (OPD) of Government Yoga and Naturopathy Medical College & Hospital, Arumbakkam, Chennai. Based on the inclusion and exclusion criteria, those subjects satisfying diagnostic criteria for Type 2 Diabetes Mellitus with their willingness were subjected for the study.

Ethical considerations

Ethical clearance

Ethical clearance was sought from the Institutional Ethical Committee prior to the start of the study and the approval for the same was granted.

Written Informed consent

Subjects who fulfilled inclusion criteria were appraised about the purpose of the study and rights as research subjects. Informed consent form was administered in English. Adequate

time was given to each patient to go through the information sheet and their queries were answered. Their right to withdraw from the study and the need for willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent.

(A sample information sheet and consent form is enclosed in Annexure)

CRITERIA FOR SAMPLE SELECTION

CRITERIA FOR DIAGNOSIS:

Diagnosis of diabetes and pre-diabetes (pearson & McCrimmon,2014)

Diabetes confirmed by either plasma glucose in random sample or 2 hrs after a 75gms glucose load ≥ 11.1 mmol/L (200mg/dl)

OR

Fasting plasma glucose ≥ 7.0mmol/L (126 mg/dl)

In asymptomatic patients two diagnostic tests are required to confirm diabetes.

Pre-diabetics is classified as

- Impaired fasting glucose = fasting plasma glucose > 6.0mmol/L(180 mg/dl) and <7.0 mmol/L(126mg/dl)

- Impaired glucose tolerance =fasting plasma glucose < 7.0 mmol/L(126mg/dl) and two hours glucose after 75gms oral glucose drink 7.8 – 11.1mmol/L(140-200 mg/dl)

TABLE:3 Oral Glucose Tolerance Test (OGTT) - venous plasma glucose

	Fasting	**2hrs after glucose load**
Fasting Hyperglycaemia	**6.1-6.9 mmoL/L (110-125 mg/dL)**	**<7.8 mmol/L (<140mg/dL)**
Impaired Glucose Tolerance	**<7.0 mmoL/L (<126 mg/dL)**	**7.8-11.0 mmoL/L (140-199 mg/dL)**
Diabetes	**>7.0 mmoL/L (> 126 mg/dL)**	**>11.1 mmoL/L (>200mg/dL)**

Inclusion and Exclusion criteria

Inclusion Criteria:

- Age group :35 to 55 years
- Both gender
- Peoples who are willing to participate in study
- BMI between 25-29.9 kg/m^2
- Subjects diagnosed with diabetes within 5 years
- Blood pressure <159/<99 mm Hg (stage 1)
- HbA1c less than 8%

- Subjects who are taking alcohol will be included in the study. However, their consumption of tobacco and alcohol will be monitored throughout the study duration.

Exclusion Criteria:

- Subjects on insulin
- Gestational diabetes
- Subjects diagnosed with any mental illness
- Subjects diagnosed with clinical illness other than mentioned above
- Had undergone life style management therapies or acupressure treatments in past three months
- Subjects undergone hospitalization or surgery in the past 6 months.

Study design

Type of the design : A randomized control trail

Randomization : Simple randomization was done using lottery method.

Allocation of patients into study and control groups : After obtaining informed consent, participants who fit the inclusion criteria will be randomly allocated into GROUPA (meridian massage group) (n=30), GROUP B (control group) (n=30). GROUP A will receive meridian massage 20 minutes per day between 11.00 am - 1.00 pm, once in a week

for 3 months along with their regular allopathic medications. GROUP B will be continuing the conventional allopathic medicines.

Trial Profile

ASSESSMENT OF OBJECTIVE VARIABLE

The pre-interventional (baseline) and post-interventional (end point) assessment of the objective variable viz. Fasting Blood Glucose (FBG) , Post-Prandial Blood Glucose(PPBG) and serum HbA1c level were done.

ASSESSMENT INTERVAL

The pre-interventional baseline data were collected on day 1 ,before the selected subjects being subjected to the intervention and the post- interventional end point data were collected on the last day of the study(at the end of 3 months) after completion of intervention. Both the baseline and end point data were collected from subjects of both groups (Group A and Group B) separately.

INTERVENTION

TEST INTERVENTION

The selected subjects after allocated into two groups , Group A subjects received weekly once meridian massage for three months and Group B subjects continued their regular conventional medications for three months.

PROCEDURE OF TEST INTERVENTION FOR GROUP A

Meridian Massage or Tui-Na is a traditional Chinese therapeutic massage technique and has been used since 2700 BC. The term “massage” indicates pressing, rubbing, and scrubbing using the hands. The Tui-Na massage techniques have been used to improve circulation of the qi, blood and metabolism and to treat several diseases.

Meridian Massages were administered one time in week for 20 min over a period of 3 months. For Tui-Na massage, the subjects were positioned straight on the massage table. Hand manipulations, including rolling (Gun Fa), the one-finger pushing method (Yi Zhi Chan Fa), and scrubbing (Ca Fa), were then performed at a frequency of 60 times per minute on TW(nail corner of ring finger to lateral end of eyebrow) and REN meridian (upper border of pubis to chin).

DATA EXTRACTION & ANALYSIS

DATA EXTRACTION

DATA MANAGEMENT

The collected baseline and end-point data of the outcome variable were managed in Microsoft Excel sheet (Version 2010)

DATA ANALYSIS:

For continuous data such as age, the descriptive statistics n, Mean and SD was presented. Normality test was done by Kolmogorov-Smirnov Z. Based on the normality of data; the non-parametric paired sample t test was applied to the data.

All tests was two-sided at $\alpha=0.05$ level of significance. All analyses were done using Statistical Package for Social Services (SPSS) software Version 16.0 (Armonk, NY: IBM Corp).

RESULT

5. RESULT

The present study was conducted to evaluate the efficacy of SANJIAO and REN meridian massage in the management of type 2 diabetes mellitus. The efficacies of the interventions were assessed based on the outcome variables viz. Fasting Blood Sugar(FBS), 2-hour Post-Prandial Blood Sugar (2-hrPPBS) and glycated hemoglobin (HbA1c) for all the statistical analysis 95% confidence interval is used and the 'p' value <0.001 is considered to be as statistically significant.

The extracted baseline and end-point data were analyzed using paired 't' test to evaluate the outcome within the group and two-sample 't' test with equal variences to compare and evaluate the outcome of the intervention between the group.

There is strong evidence that the meridian massage intervention showed statistically significant changes in fasting blood sugar level ($t = 5.660$, $p = 0.001$), postprandial blood sugar level ($t = 5.764$, $p = 0.001$) and HbA1C ($t = 5.724$, $p = 0.001$). In this data set, it reduces fasting blood sugar, postprandial blood sugar level and HbA1C, on average, by approximately 6.1, 11.6 and 0.38 points, respectively. It is important to look at the 95% Confidence Interval (95% CI). In this study, the 95% CI is from 7.4 to 15.7. This confirms that, although the difference in fasting blood sugar level, postprandial blood sugar level and HbA1C is statistically significant and it is actually relatively small.

STATISTICAL DATA ANALYSIS

For continuous data such as age, the descriptive statistics n, Mean and SD was presented. Normality test was done by Kolmogorov-Smirnov Z. Based on the normality of data, the non-parametric paired sample t test was applied to the data.

All tests was two-sided at $\alpha=0.05$ level of significance. All analyses were done using Statistical Package for Social Services (SPSS) software Version 16.0 (Armonk, NY: IBM Corp).

Age distribution

Table 4: Patients' Demographic characteristics at baseline

Parameter	Group	N	Mean ± SD
Age	Control	30	45.33 ± 4.71
	Study	30	44.90 ± 5.30
Height	Control	30	162.47 ± 5.78
	Study	30	162.40 ± 4.25
Weight	Control	30	72.73 ± 5.86
	Study	30	73.48 ± 5.14
BMI	Control	30	27.53 ± 0.87
	Study	30	27.85 ± 1.16

Interpretation

Table 1 shows the anthropometry parameters in acupuncture group and control group. In both the groups, the mean difference noticed in all the parameters like Weight (72.73 ± 5.86 kg vs 73.48 ± 5.14) and BMI (27.53 ± 0.87 kg/m2 vs 27.85 ± 1.16 kg/m2) and they were considered for the comparison.

Table 5: Between group comparison (Baseline data)

Parameter	Group	N	Mean ± SD
Pre FBS	Control	30	117.63 ± 12.86
	Study	30	121.37 ± 15.62
Pre PPBS	Control	30	154.23 ± 9.40
	Study	30	173.20 ± 40.59
Pre HbA1C	Control	30	7.30 ± 0.42
	Study	30	7.10 ± 0.419

Interpretation

Table 2 shows the baseline parameters (pre FBS, PPBS and HbA1C) in acupuncture group and control group. In both the groups, the mean difference noticed in all the parameters like fasting blood sugar (117.63 ± 12.86 mmHg vs 121.37 ± 15.62 mmHg), postprandial blood

sugar (154.23 ± 9.40 mmHg vs 173.20 ± 40.59 mmHg) and HbA1C (7.30 ± 0.42 vs 7.10 ± 0.419) and they were considered for the comparison.

Table 6: Between group comparison (Post Intervention)

Parameter	Group	N	Mean ± SD
Post FBS	Control	30	104.43 ± 13.45
	Study	30	115.27 ± 15.10
Post PPBS	Control	30	142.67 ± 11.55
	Study	30	161.60 ± 36.15
Post HbA1C	Control	30	6.62 ± 0.35
	Study	30	6.72 ± 0.410

Interpretation

Table 3 shows the post intervention parameters (post FBS, PPBS and HbA1C) in acupuncture group and control group. In both the groups, the mean difference noticed in all the parameters like fasting blood sugar (115.27 ± 15.10 mmHg vs 115.27 ± 15.10 mmHg), postprandial blood sugar (142.67 ± 11.55 mmHg vs 161.60 ± 36.15 mmHg) and HbA1C (6.62 ± 0.35 vs 6.72 ± 0.410) and they were considered for the comparison.

Table 7: Between groups comparison using Paired Sample t test.

Parameter	Group	N	Mean ± SD	P value
PREFBS – POSTFBS	Control	30	13.200 ± 9.114	0.001
	Study	30	6.100 ± 5.904	
PREPPBS – POSTPPBS	Control	30	11.56 ± 9.44	0.001
	Study	30	11.60 ± 11.02	
Post HbA1C	Control	30	0.67 ± 0.24	0.001
	Study	30	0.38 ± 0.36	

Interpretation

There is an evidence to show the statistically significant difference between groups on the following parameters – fasting blood sugar, postprandial blood sugar and HbA_1C.

Table 8: Mean differences of Study group

Study Group	95% Confidence Interval of the Difference		T	df	Sig. (2-tailed)
	Lower	Upper			
PREFBS & POSTFBS	3.896	8.304	5.660	29	0.001
PREPPBSS & POSTPPBS	7.484	15.716	5.764	29	0.001
PREHbA1C & POSTHbA1C	.246	.520	5.724	29	0.001

Interpretation

There is strong evidence that the meridian massage intervention showed statistically significant changes in fasting blood sugar level (t = 5.660, p = 0.001), postprandial blood sugar level (t = 5.764, p = 0.001) and HbA1C (t = 5.724, p = 0.001). In this data set, it reduces fasting blood sugar, postprandial blood sugar level and HbA1C, on average, by approximately 6.1, 11.6 and 0.38 points, respectively. It is important to look at the 95% Confidence Interval (95% CI). In this study, the 95% CI is from 7.4 to 15.7. This confirms that, although the difference in fasting blood sugar level, postprandial blood sugar level and HbA1C is statistically significant and it is actually relatively small.

Figure 1 :AGE DISTRIBUTION IN STUDY GROUP

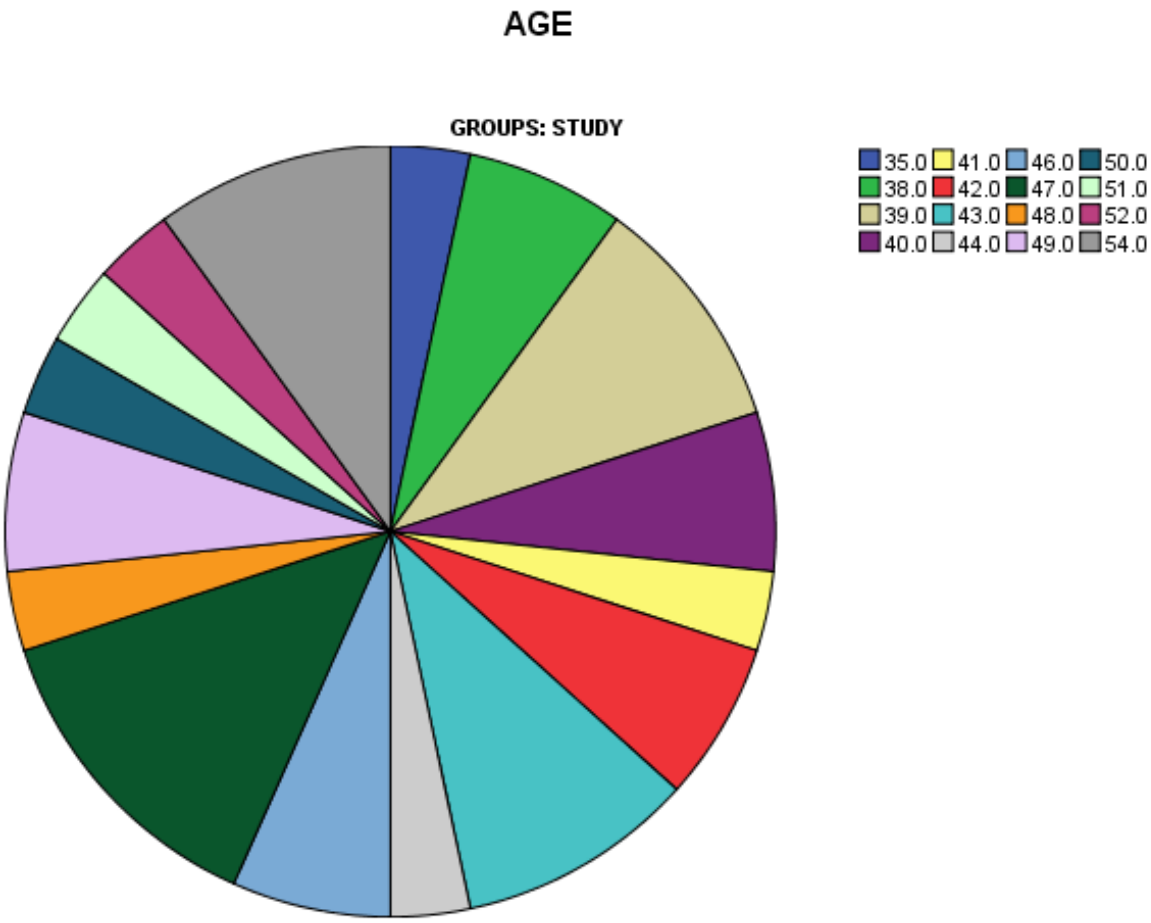


Figure 2: AGE DISTRIBUTION IN CONTROL GROUP

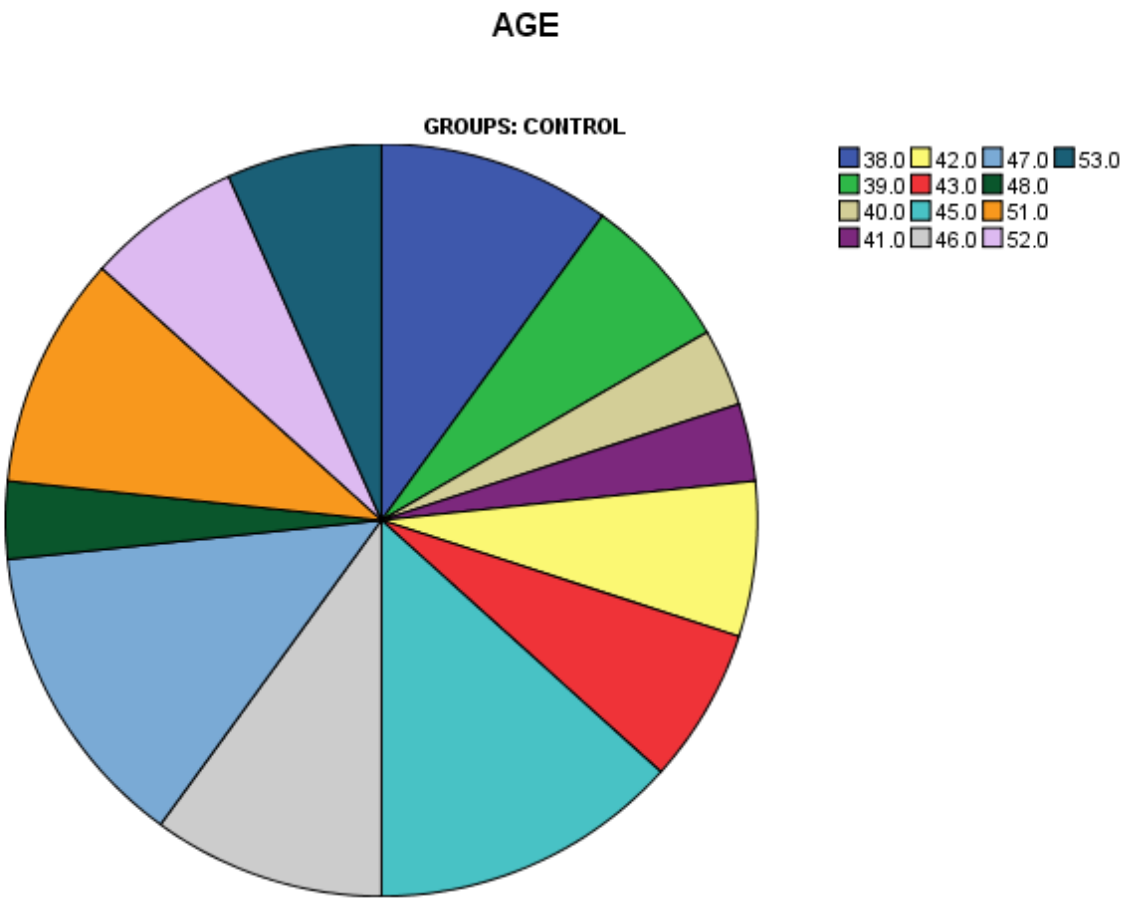


FIGURE 3: BMI DISTRIBUTION IN CONTROL GROUP

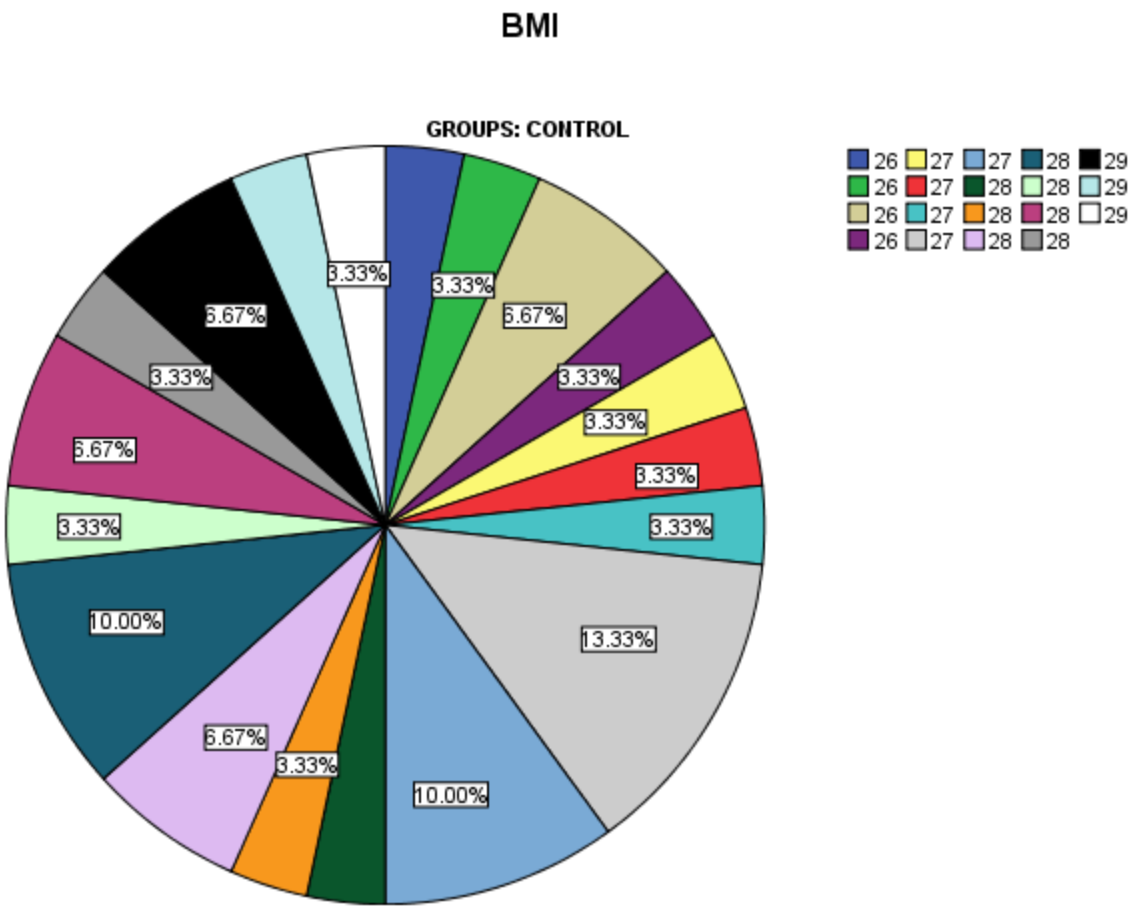
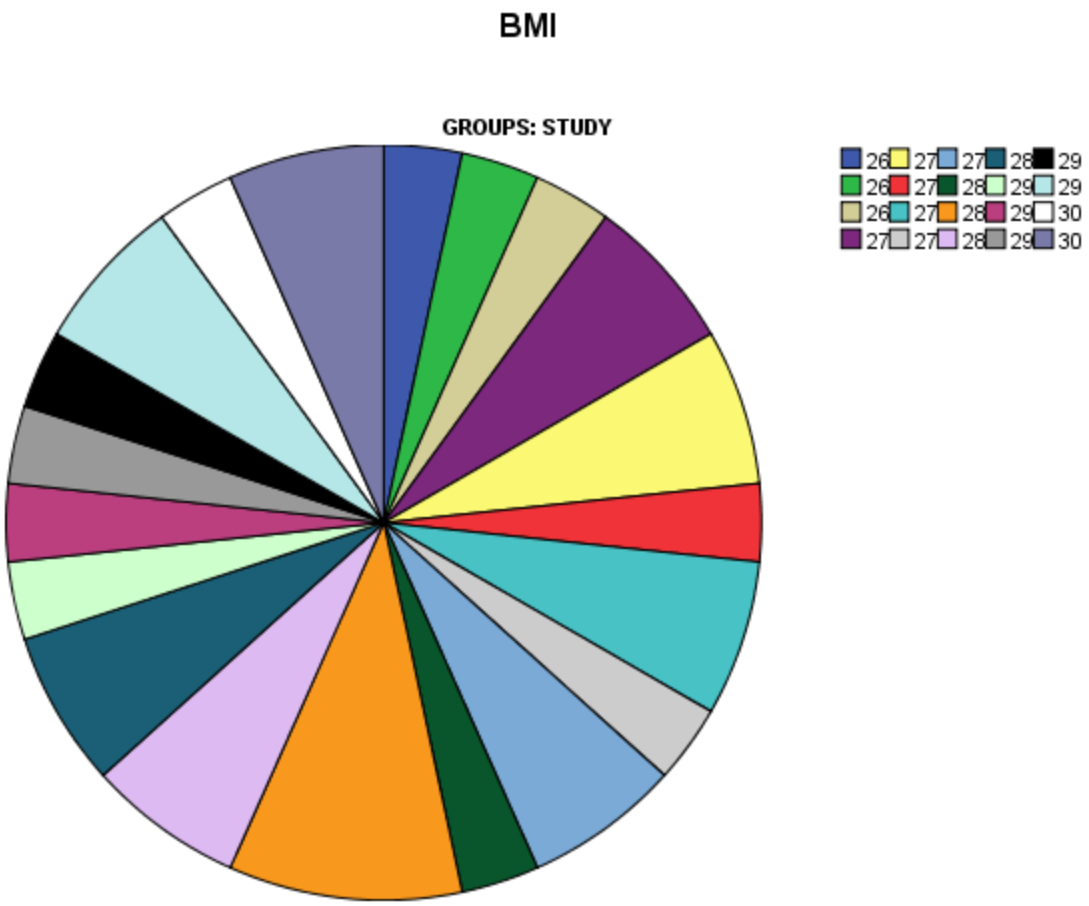


FIGURE 4: BMI DISTRIBUTION IN STUDY GROUP



DISCUSSION

6. DISCUSSION

The objective of this RCT was to establish the effects of Traditional Chinese medicine on Type 2 Diabetes Mellitus (type 2 diabetes) with a focus on the effects of Meridian massage. Acupuncture is widely applied in clinical practice for insulin resistance related diseases such as obesity, diabetes and related complications, PCOS and hypertension (Cho et al., 2009; Wang et al., 2008; Stener- Victorin et al., 2008; Lee et al., 2009).

The present study was done to evaluate the outcome of meridian massage among type2diabetes mellitus. A statistically significant changes was observed in the biochemical parameters (outcome variable) viz. Fasting Blood Sugar, Post Prandial Blood Sugar and HbA1c level.

In one study it was observed that acupuncture has been effectively used, though the focus has been more on the effects of acupuncture on peripheral neuropathy as a result of Type 2 Diabetes than on improving glucose tolerance levels and A1c percentages (Al Rowais, 2001; Qin,2003; Li, 2013;)

Implications for Theory

The research on TCM treatments for type 2 diabetes has been ongoing for several decades, yet remains in the developmental stages due to the complexity of the situation. Even though there is no clinical evidence that Western medications for diabetes and Chinese herbal therapies are incompatible, there is concern that when combining the two, blood sugar levels may decline too far (Dharmananda, 2003). While Chinese medical literature occasionally mentions the use of Chinese herbs along with Western medications, specific strategies for combining the two are not commonly presented.

Acupuncture is a common approach to treating diabetes in China. However, the efficacy and indications for acupuncture have been controversial because of scientific, historical and philosophical differences. The assumption is that acupuncture is only suitable for pain management, perhaps because the initial introduction to acupuncture in the Western world was mainly for this application. Therefore, relatively few people realize the broad spectrum of diseases and maladies that acupuncture can not only treat but also effectively work in conjunction with Western medications for the health and betterment of patients.

Of the studies examined regarding the efficacy of acupuncture on type 2 diabetes, two discussed the effects of acupuncture on diabetic peripheral neuropathy. In one study (Tong et al., 2010), 42 cases treated with acupuncture were compared with 21 exposed to

sham acupuncture over a period of 15 days. In the other study (Abuaisha et al., 1997), 46 diabetic patients with chronic peripheral neuropathy were treated with acupuncture over a period of 10 weeks. Though this particular study reported that there were no significant changes in vibratory perception threshold (VPT) or in HbA1c percentages in patients studied during the course of the treatment, both studies reported evidence that acupuncture may be considered as an effective and safe therapy and modality for the treatment of chronic peripheral diabetic neuropathy.

In a review article (Liang et al., 2010) 234 English publications on the PubMed database between 1979 and 2009 were reviewed to determine the effectiveness of acupuncture as a treatment for insulin resistance diseases, which included obesity, type 2 diabetes, hypertension, polycystic ovary syndrome (PCOS), non-alcohol fatty liver diseases (NAFLD) and metabolic syndrome. The review authors determined that those studies concluded that acupuncture was beneficial and effective as a treatment modality for type 2 diabetes, and that patients with type 2 diabetes seemed to respond better to acupuncture than patients with Type 1 diabetes. Type 2 diabetes patients showed improved clinical manifestations as well as reduction in fasting blood sugar levels and improvement in oral glucose tolerance tests.

Since it is such a common and increasingly prevalent condition, continuing education sessions for TCM practitioners should include specific focus on the treatment of type 2 diabetes. As of 2010, an estimated 285 million people had diabetes globally, with type 2 making up about 90 percent of the cases. By 2030, this number is estimated to

almost double (Wild et al., 2004). Chinese medicine, especially when working hand in hand with Western medicine, is certainly one of the answers to handling this disease. Over the ages, effective acupuncture points have been formulated to treat diabetes. Continuing education sessions can also help to keep practitioners in touch and up to date with these excellent treatments and make other practitioners aware regarding their use.

Altogether, the meridian massage on REN and TW meridian among type 2 diabetic subjects showed, a significant improvement in blood sugar level and HbA1c level. Further, from the difference in the fasting and post-prandial blood sugar level and HbA1c level of Group A and Group B it is inferred that the subjects treated with meridian massage along with conventional medication is more effective in reducing blood sugar level and HbA1c level. however, the large number of sample is necessary to reaffirm the assertion.

STRENGTH OF STUDY

The following were the strength of the study;

- Effective randomization
- Equally distributed group of subjects
- Significant improvement in outcome variable
- No adverse reaction occurred during study.

LIMITATION

- Smaller sample size
- Blinding was not possible Subjects were not on diet plan

FUTURE DIRECTION OF THE STUDY

Study can be conducted with larger sample size.

A multi-armed study comparing Acupuncture, Yoga and role of herbs in treating Type 2 Diabetes Mellitus.

CONCLUSION

7. CONCLUSION

The present study has revealed that Meridian massage is effective in reducing the blood sugar level and HbA1c level among Type2 diabetes.

The effects of Traditional Chinese Medicine on diabetes have been well documented in Chinese Medical classics for centuries. Due to the nature of contemporary medicine, we need concrete Western scientific model data and evidence gathering to demonstrate the efficacy of Chinese medicine in the treatment of diabetes and its affect on blood glucose levels

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ANNEXURE

INFORMATION SHEET

We are conducting a study **"**EFFICACY OF SANJIAO AND REN MERIDIAN MASSAGE ON BLOOD SUGAR LEVEL AMONG TYPE2 DIABETICS - A RANDOMIZED CONTROL TRIAL *"* at Government Yoga and Naturopathy Medical College Hospital, Chennai – 106.

The purpose of this study is to evaluate the effectiveness of meridian massage on serum blood glucose level and HbA1c level .We need your participation in this study.

The privacy of the participants in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefit to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator

Signature of participant

Date:

INFORMED CONSENT FORM

Title of the study: "EFFICACY OF SANJIAO AND REN MERIDIAN MASSAGE ON BLOOD SUGAR LEVEL AMONG TYPE2 DIABETICS - A RANDOMIZED CONTROL TRIAL **"**

Name of the Participant:

Name of the Principal Investigator: Dr.N.PRABU

Name of the Institution: Government Yoga & Naturopathy Medical College, Chennai – 600 106

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am exercising my free power of choice, hereby give my consent to be included as a participant in **: "**EFFICACY OF SANJIAO AND REN MERIDIAN MASSAGE ON BLOOD SUGAR LEVEL AMONG TYPE2 DIABETICS - A RANDOMIZED CONTROL TRIAL **"**

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I have not participated in any research study within the past _____month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understood that my identity will be kept confidential if my data are publicly presented.

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____

Date_____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____

Date_____

INFORMATION TO PARTICIPANTS

Investigator: Dr. N.PRABU

Name of Participant:

Title:

"EFFICACY OF SANJIAO AND REN MERIDIAN MASSAGE ON BLOOD SUGAR LEVEL AMONG TYPE2 DIABETICS - A RANDOMIZED CONTROL TRIAL **"**

You are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted in Government Yoga & Naturopathy Medical College, Chennai – 600 106.

What is the Purpose of the Research?

The purpose of this study is to evaluate the effect of SANJIAO and REN meridian massage on serum blood glucose and HbA1c in type 2 diabetes.

The Study Design:

Comparative study with 60 subjects treated with meridian massage.

Study Procedures:

Participants will be initially assessed for serum blood glucose level and HbA1c level , followed by interventions and reassessments.

Possible Risks to you: nil

Possible benefits to you:

Diabetes can be managed effectively through meridian massage and help prevent from complications from diabetes.

Possible benefits to other people:

The result of the research may provide benefits to the society in terms of advancement of medical knowledge.

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

How will your decision to not participate in the study affect you?

Your decisions to not to participate in this research study will not affect your medical care or your relationship with investigator or the institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping the treatment.